REMARKS

Applicants respectfully request that the Examiner forward a copy of the PTO form 1449 (mailed January 3, 2000) indicating that the Examiner has reviewed each of the references submitted. The Office Action mailed June 20, 2001 indicated that said form 1449 was an attachment, but Applicants did not receive a copy.

Upon entry of this paper, no claims have been amended, claims 28-43 have been canceled, and no claims have been added as new claims. Thus, claims 1-27 and 44-52 are presently pending in this application. No new matter has been added. The cancellation of claims 28-43 should in no way be construed to be an acquiescence to any of the rejections stated. Claims 28-43 are being canceled solely to expedite the prosecution of the present application as being directed toward non-elected subject matter. Applicants reserve the option to further prosecute the same or similar claims in the instant or a subsequent patent application.

Affirmation of Election

During a telephone conversation on June 12, 2001, provisional election was made to prosecute the invention of the device and claims 1-27 and 44-52. Applicants hereby affirm this election. Claims 28-43 have been canceled in this Amendment in accordance with this election to further prosecution of this Application.

Applicants expressly reserve the right to, at a later date, prosecute either as part of an allowed generic claim and/or as dependent claims, the remaining species of the present invention under 37 C.F.R. §1.141. Applicants further expressly reserve the right to file at a later date, one or more divisional applications under 35 U.S.C. §121, directed to the subject matter of any canceled claims.

Summary of Invention in Pending Application

Prior to discussing the substantive rejections below, applicants wish to provide a brief summary of what they regard as their invention as claimed in the pending application.

The claimed invention provides a radially expandable fluid delivery device for delivering fluid to a treatment site within the body. The radially expandable fluid delivery device can be used, for example, as a catheter delivered balloon for the treatment of body lumens, organs, and grafts. Fluids, including therapeutic agents, can be delivered through the walls of the fluid delivery device to effect localized treatment of sites within the body. The fluid delivery device of the present invention is constructed of a biocompatible material having a microstructure that can provide a controlled, uniform, low-velocity distribution of fluid through the walls of the fluid delivery device to effectively deliver the fluid to the treatment site without damaging tissue proximate the walls of the device.

In accordance with one aspect of the present invention, the fluid delivery device comprises a member constructed of a biocompatible material. The member is defined by a wall having a thickness extending between an inner and an outer surface. The wall is characterized by a microstructure of nodes interconnected by fibrils. The member is deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon the introduction of a pressurized fluid to the lumen. The member includes at least one microporous portion having a porosity sufficient for the pressurized fluid to permeate through the wall. The spaces between the nodes control the permeation of fluid through the wall of the fluid delivery device. In a preferred embodiment, substantially all of the nodes within the microporous portion are oriented such that spaces between the nodes form generally aligned micro-channels extending from the inner surface to the outer surface of the wall.

In accordance with another aspect of the present invention, the nodes within the microporous portion of the member can be oriented substantially parallel to the longitudinal axis of the member. The micro-channels are preferably sized to permit the passage of the pressurized fluid from the inner surface to the outer surface of the wall. The size of the microchannels within the microporous portion can be varied longitudinally and/or circumferentially to provide regions of increased porosity within the microporous portion. The presence of regions of differing porosity allows the volume of fluid delivered through the microporous portion of the member to vary, longitudinally and/or circumferentially, across the microporous portion. This allows the microporous portion to be specifically tailored to the size and shape of the site being treated.

Claim Rejections under 35 U.S.C. §102

Claims 1, 3, 4, 6-20, 24-37, and 44

Claims 1, 3, 4, 6-20, 24-37, and 44 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,336,178 to Kaplan (Kaplan '178). This anticipatory rejection is respectfully traversed in view of the following comments.

Summary of Kaplan '178

Kaplan '178 is directed to an intravascular catheter providing means for infusing an agent into a treatment site in a body lumen and means for deploying the infusing means adjacent the treatment site, which operate independently of one another. A flexible catheter body has an expansion member attached to its distal end in communication with an inflation passage and an infusion array disposed about the expansion member in communication with one or more delivery passages. The infusion array includes a plurality of delivery conduits having laterally oriented orifices. The delivery conduits may be extended radially from the catheter body to contact a treatment

site by expanding the expansion member with an inflation fluid. An agent may be introduced into the delivery passages and infused into the treatment site through orifices in the delivery conduits. The expansion member may be expanded for dilatation of the lumen before, during, or after infusion.

The Claimed Invention Is Novel With Respect To Kaplan '178 Because Kaplan '178 Does Not Teach All of the Claimed Elements Of The Present Invention

Where the present invention utilizes a single wall having a microstructure of nodes and fibrils with microporous characteristics, Kaplan '178 utilizes a first wall having delivery channels drilled therethrough. The delivery channels are not microporous in nature. Further, the first wall of the Kaplan '178 device is expanded with a second wall of an inflatable balloon. These approaches substantially differ from the present invention, and therefore Kaplan '178 cannot anticipate the present claimed invention.

More specifically, the present invention comprises, among other elements, a single member having a microstructure of nodes interconnected by fibrils. In at least one microporous portion of the microstructure the porosity is sufficient for fluid to permeate through the wall of the member. There is no disclosure in Kaplan '178 of "a member constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils . . . wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall." *See* Independent Claims 1, 25-27, and 44.

In addition, the present invention maintains a wall wherein substantially all of the nodes within a microporous structure are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall. Kaplan '178 does not disclose a device, "wherein the wall of the member includes at least

one microporous portion having a porosity sufficient for a fluid to permeate through the wall, spaces between the nodes substantially controlling the permeation of fluid through the wall." *See* Independent Claims 1, 25-27, and 44.

In light of the above comments, applicants respectfully submit that Claims 1, 25-27, and 44 of the present invention are not anticipated by, and are therefore in condition for allowance over, the cited document. Dependent Claims 3, 4, 6-20, and 24 ultimately depend from Claim 1, and are therefore allowable over the cited reference based on their dependency on an allowable claim, in addition to their own claimed characteristics as detailed in each dependent claim.

Claims 1-4, 6-10, 13-20, 24-27, and 44-49

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,843,069 to Butler et al. (Butler '069). This anticipatory rejection is respectfully traversed in view of the following comments.

Summary of Butler '069

Butler '069 is directed to an implantable containment apparatus made of selectively permeable material. In particular, the implantable containment apparatus is used to contain a therapeutical device, such as a drug delivery device, a cell encapsulation device, or a gene therapy device. A therapeutical device can be placed and replaced in an apparatus of the present invention without damaging tissues associated with the selectively permeable material of the apparatus.

The Claimed Invention Is Novel With Respect To Butler '069 Because Butler '069 Does Not Teach All of the Claimed Elements Of The Present Invention

Butler '069 does not disclose a radially expandable fluid delivery device. Rather, Butler '069 discusses an implantable, selectively permeable, containment apparatus used to contain other devices. The device of the present invention is not implanted in a patient, but rather is used during a medical procedure and removed upon conclusion of the procedure.

More specifically, Butler '069 does not disclose, "[a] radially expandable fluid delivery device comprising: a member constructed of a biocompatible material, . . . the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration . . ." *See* Independent Claim 1, and *see also* Independent Claims 25-27, and 44.

Where the present invention utilizes a single wall, monolithic, inflatable member, the device of Butler '069 describes at least a two piece apparatus consisting of "an implantable containment apparatus in the form of a tube comprised of a selectively permeable polymer material having an exterior surface, an interior surface defining a luminal space of substantially uniform diameter, and an access means at each end of the tube that permits access to the luminal space of the tube . . ." Butler '069, column 4, lines 28-34.

Butler '069 does not disclose a single member drug delivery device that does not remain in a patient's body as an implant. Rather, Butler '069 describes "an implantable containment apparatus . . . that permits a therapeutical device, such as a drug delivery, a gene therapy, or a cell encapsulation device, to be placed and replaced in a recipient . . ." Butler '069, column 3, lines 28-32. Butler '069 describes an implantable housing that supports a drug delivery device, while the present claimed invention is a drug delivery device that does not require such an implanted housing for operation.

In light of the above comments, applicants respectfully submit that Claims 1, 25-27, and 44 of the present invention are not anticipated by, and are therefore in condition for allowance over, the cited document. Dependent Claims 2-4, 6-10, 13-20, 24, and 45-49 ultimately depend from Claims 1 and 44 and are therefore allowable over the cited reference based on their dependency on allowable claims, in addition to their own claimed characteristics as detailed in each dependent claim.

Claim Rejections under 35 U.S.C. §103

Claims 5, 21-23, and 50-52

Claims 5, 21-23, and 50-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Butler '069. This rejection is respectfully, but most strenuously traversed in view of the following comments.

The Claimed Invention Is Non-Obvious With Respect To Butler '069 Because Butler '069 Does Not Teach Or Suggest All of the Claimed Elements Of The Present Invention

To reiterate a previous point, Butler '069 does not disclose a single member drug delivery device that does not remain in a patient's body as an implant. Rather, Butler '069 describes "an implantable containment apparatus . . . that permits a therapeutical device, such as a drug delivery, a gene therapy, or a cell encapsulation device, to be placed and replaced in a recipient . . ." Butler '069, column 3, lines 28-32. Butler '069 describes an implantable housing that supports a drug delivery device. Contrarily, the present claimed invention is a "radially expandable fluid delivery device", where the fluid delivered can be a drug; and the present invention does not require such an implanted housing for operation.

Claims 5 and 21-23 all depend from allowable independent Claim 1, and therefore are allowable based on their dependency in addition to their own characteristics. For example, Claim 5 is directed to internodal distance of 1μm to 150 μm, while Claims 21-23 are directed to different hydraulic conductivity amounts.

CONCLUSION

Each of applicants' claims contains characteristics that are neither disclosed nor suggested by the cited documents. For the reasons detailed herein, applicants respectfully request that all rejections be reconsidered and withdrawn. This application is in condition for allowance, and notice of the same is earnestly solicited. Should the examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the examiner is invited to contact applicants' representative by telephone at the number indicated below.

Attached hereto is a marked-up version of any changes made to the Specification and/or Claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 28-43 have been canceled without prejudice or disclaimer of the subject matter therein.